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# Robot-based psychological intervention program for the prevention of sexual abuse in children

**Submission date**
19/06/2020

**Recruitment status**
No longer recruiting

**Registration date**
15/07/2020

**Overall study status**
Completed

**Last Edited**
15/09/2023

**Condition category**
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims:
Child sexual abuse is a serious issue with serious consequences. Self-care education programs can improve children's awareness, knowledge, and skills to defend themselves against sexual abuse. The aim of this study is to evaluate a psychological intervention program with a smart robot for sexual care in elementary school children.

Who can participate?
Children aged 8-12 (elementary school) in Ghaenat City, Iran in 2019

What does the study involve?
Children are randomly allocated to the test and control groups. First, all students fill in a questionnaire. The participants in the test group attend 10 45-minute sessions of psychological intervention (with robots) in 5 weeks (two sessions per week). At the beginning of each session, the researcher explains the session's topic and then a robot teaches the content of the session via tools such as PowerPoints and movies. The material related to each session is emphasized after the training, and finally, the educational content of each session is reviewed and the possible questions and tasks of the previous session are answered. In the end, assignments are allocated to the participants to practice the skills learned during the session. On the other hand, no intervention is carried out for the participants in the control group. After the education process, both groups fill the questionnaire again. Three months after the intervention, all of the participants fill the questionnaire one more time as the follow-up stage. Educational sessions are held for the control group at the end of the study.

What are the possible benefits and risks of participating?
The benefits of this intervention are prevention and awareness of child sexual abuse. There is no risk to the participants.

Where is the study run from?
Private center, Khorasan, Ghaenat (Iran)

When is the study starting and how long is it expected to run for?
February 2019 to December 2019

Who is funding the study?
Investigator-initiated and funded

Who is the main contact?
Mohammad Tahan
t.mohammad2@gmail.com

# Contact information

### Type(s)
Scientific

### Contact name
Mr Mohammad Tahan

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
Nil known

# Study information

### Scientific Title
Effectiveness of a robot-based psychological intervention program on sexual care in elementary-school children

### Study objectives

Does a robot psychological interventional program affect the sexual care of elementary school children?

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 28/07/2019, Iran National Committee for Ethics in Biomedical Research (Islamic Azad University, Bojnourd Branch - Research Ethics Committee, Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran; +98 (0)21 81455618; ethics@behdasht.gov.ir), ref: IR.IAU.BOJNOURD.REC.1398.004

## Study design
Quasi-experimental research with a pretest-posttest design and a control group

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Other

## Study type(s)
Prevention

## Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

## Health condition(s) or problem(s) studied
Sexual care of elementary school children

## Interventions
After receiving a license from the vice-chancellor for research and technology of Islamic Azad University, Birjand Branch, ethical code in research, and permission from the head of education in Qaen and communicating with elementary schools of the city, parents suggested by teachers are invited to participate in a briefing meeting to explain research objectives and implementation stages. Written informed consent is obtained from all parents and they are ensured of the confidentiality terms regarding their personal information. In a meeting, 80 children are selected and allocated to two test and control groups. First, all students fill the questionnaire and the scores obtained are considered as a pretest. The participants in the test group attend 10 45-minute sessions of psychological intervention (with robots) in 5 weeks (two sessions per week). The first session is held in Payam Salamat Clinic. At the beginning of each session, the researcher explains the session’s topic and then a robot teaches the content of the session via tools such as PowerPoints and movies. The material related to each session is emphasized after the training, and finally, the educational content of each session is reviewed and the possible questions and tasks of the previous session are answered. In the end, assignments are allocated to the participants to practice the skills learned during the session. On the other hand, no intervention is carried out for the participants in the control group. After the

education process, both groups fill the questionnaire again and the scores are considered as a posttest. Three months after the intervention, all of the participants fill the questionnaire one more time as the follow-up stage. In order to adhere to research principles, educational sessions are held for the control group at the end of the study. A summary of the content of each session is presented in:

1. Training program -Introduction to robots
2. Introducing, familiarizing and informing about body parts
3. Identifying, informing and becoming acquainted with important and private body parts
4. Learning to recognize people (distinguishing family members, acquaintances and strangers)
5. Learning how to connect with family members, acquaintances and strangers
6. Identifying dangerous and harmful situations and moments
7. Identifying and introducing dangerous and harmful situations and moments and how to deal with them (family)
8. Identifying and introducing dangerous and harmful situations and moments and how to deal with them (acquaintances)
9. Identifying and introducing dangerous and harmful situations and moments and how to deal with them (strangers)
10. Overviewing past topics and reviewing all items considered

### Intervention Type
Behavioural

### Primary outcome measure
Children's knowledge and awareness of sexual abuse measured using Questionnaire of Children's Knowledge and Awareness of Sexual Abuse at 6 months

### Secondary outcome measures
There are no secondary outcome measures

### Overall study start date
27/02/2019

### Completion date
20/12/2019

## Eligibility

### Key inclusion criteria
1. Willingness to participate in the study
2. Aged 8-12 years
3. No history of acute psychological and physical diseases (based on interviewing and health checklist of students)
4. Consent form completed by parents

### Participant type(s)
Other

### Age group
Child

### Lower age limit
8 Years

### Upper age limit
12 Years

### Sex
Both

### Target number of participants
80 participants (40 female and 40 male)

### Total final enrolment
80

### Key exclusion criteria
1. Absence from one educational session
2. Taking specific drugs
3. Simultaneous participation in a similar educational intervention
4. Unwillingness to participate in the research

### Date of first enrolment
01/08/2019

### Date of final enrolment
20/12/2019

## Locations

### Countries of recruitment
Iran

### Study participating centre
### Private center
Khorasan
Ghaenat
Iran
97616

## Sponsor information

### Organisation
Islamic Azad University of Birjand

### Sponsor details

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**Sponsor type**
University/education

**Website**
http://iaubir.ac.ir

**ROR**
https://ror.org/02p42am41

# Funder(s)

**Funder type**
Other

**Funder Name**
Investigator initiated and funded

# Results and Publications

**Publication and dissemination plan**
Planned publication in high-impact peer-reviewed journal.

**Intention to publish date**
30/07/2020

**Individual participant data (IPD) sharing plan**
The current data sharing plans for this study are unknown and will be available at a later date.

**IPD sharing plan summary**
Data sharing statement to be made available at a later date

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 12/02/2021 | 09/03/2022 | Yes | No |
| Protocol article | | 01/03/2023 | 15/09/2023 | Yes | No |